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HAHN LOESER & PARKS, LLP
One GOJO Plaza
Suite 300
AKRON, OH 44311-1076

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| EXAMINER |
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VU, QUYNH-NHU HOANG

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| ART UNIT | PAPER NUMBER |
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3763

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05/16/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
akron-docket@hotmail.com

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| Office Action Summary | Application No. 10/782,543 | Applicant(s) JUNGE, AGUR | |
| | Examiner QUYNH-NHU H. VU | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment filed on 3/19/08 has been entered.

Claims 1-10, 12-28 are present for examination.

Claim 11 is cancelled.

Applicant's arguments filed on 3/19/08 have been fully considered but are not persuasive.

Therefore, claims 1-10, 12-28 are rejected in the new ground rejections as set below.

Claim Objections

Claims 1-11, 12-28 objected to because of the following informalities: the recitation "sealing element" suggested to be changed to "sealing assembly". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 12-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guy et al. (US 5,334,164) in view of Stevens et al. (US 5,935,112).

Regarding claims 1 and 21, Guy discloses a variable interior dimension cannula valve, however, it can be used as an insertion catheter, since insertion catheter are usually includes an elongate flexible tube. The device comprising: sealing element 7; a tubular main body 9 of an elastic material (col. 6, lines 63-68), a peripheral wall of the main body enclosing a hollow space that extends along a longitudinal direction of the sealing element with a connecting passage 32 for fluids; wherein the peripheral wall in the

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region of the connecting passage is designed in respect of elasticity of the material, thickness of the wall and inside diameter of the hollow space, such that twisting the main body causes a constriction (at 32) of hollow space in the region of the connecting passage in such a way that the constriction is at predetermined position in relation to the longitudinal direction of the sealing element (see Fig. 6-7). Examiner is taking position that if the more twisting of the body of 9, the diameter of hollow space will be reducing and the longitudinal is shorter also.

Regarding claim 2, the tubular main body 9 comprises first and second longitudinal ends (31, 33), such that twisting of the two longitudinal ends relative to each other causes regular folding of the peripheral wall in the region of the connecting passage and concomitantly therewith a reduction in the diameter of the connecting passage, which is dependent on the amount of angular twist applied (see Figs. 6-7).

Regarding claims 3-8, the peripheral wall has a smaller wall thickness in the region of the connecting passage (at 32) than in adjacent wall regions (31, 33); and the wall thickness of the peripheral wall increases steadily with increasing distance from the connecting passage. It is noted that the connecting passage is at 32.

Regarding claims 9-10, a flange 34, 35 is located at each longitudinal end of the sealing element (Fig. 9 or 15).

Regarding claim 13, the tubular main body comprises a silicon rubber (col. 6, lines 63-68).

Regarding claim 20, the connecting passage (at 32) is fully open the hollow space is of a round diameter which is substantially uniform over the longitudinal direction so that the hollow space is in the form of a cylinder open at the two ends thereof (Figs. 3-4 or 9-12).

Regarding claims 22, an insertion opening for a shaft 24, 26 (Fig. 2, 13, 15) or a surgical instrument 50 inserted into a vessel.

Regarding claims 23-28, a control element 14 retain various, rotated position after setting thereof; the control elements latch by detents 13 (col. 4, lines 51-68).

Guy does not disclose that a diaphragm which at least partially closes at least one longitudinal end of the sealing element; wherein the diaphragm has a central opening.

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Stevens discloses, Fig. 2, a seal 44; a diaphragm 44 or 170 having a central opening and the diaphragm at least partially closes at least one longitudinal end of the sealing elements. Stevens further discloses that a second tongue 160 be configured to cooperate with first ring 170 sufficiently to form a seal between proximal end 138 of compressible seal 44 and slip ring 48 (col. 11, lines 1-10). It is noted that the ring 170 of slip ring 48 of Stevens is similar function with the diaphragm 18 serves as a second auxiliary sealing element of Application as described in para 0035. The only different between the devices of Stevens and the Application is that the ring 170 and seal 44 are two separate pieces instead of a single piece as Applicant claimed. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the seal and diaphragm in single piece, since it has been held that constructing a formerly integral in single piece structure in various elements involves only routine skill in the art (see Response to Arguments also).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Guy with a diaphragm, as taught by Stevens, in order to seal between the proximal end of compressible seal.

Regarding claims 14-19, Guy in view Stevens disclose the claimed invention except for that the tubular main body comprises a material with Shore hardness greater 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a tubular main body with a material of Shore hardness greater than 30, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Response to Arguments

1. Applicant argues that Guy does not suggest a sealing element.

In response, Guy clearly discloses a sealing element/assembly 7 or 9 (Figs. 3-8).

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2. Applicant argues that Stevens does not teach or suggest such as construction of a sealing element. Within seal 44, annular rib 158 maybe considered to correspond to the adjustable constriction of the hollow space in the claimed invention, not the diaphragm.

In response, Stevens clearly discloses a sealing element 44. Examiner denotes the diaphragm as element 170 but not the annular rib 158. Stevens further discloses that the second tongue 160 be configured to cooperate with first ring 170 sufficiently to form a seal between proximal end 138 of compressible seal 44 and slip ring 48 (col. 11, lines 2-10). This feature of Stevens can perform same function as the diaphragm 18 of Application that serves as a second auxiliary sealing element (see para 0035 of Specification).

3. Applicant argues that Stevens corresponding to the claimed diaphragm and tubular body are not comprised of a single piece.

In response, the sealing 44 and the diaphragm of Stevens are separate pieces but not comprised in a single piece. However, one skill in the art would recognize that the unification or integration involve more than mere mechanical skill or matter of obvious engineering choice. It appears to us that the unity of diversity of parts would depend more than the choice of the manufacturer, and the convenience to construct the device, than on any inventive concept.

4. Regarding about Li's reference, the rejection under Li's reference has been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763